

PATENT

**REMARKS**

Claims 1, 4-6, 7, 13, and 16 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,722,999 to Snell. Claims 2, 3, 8-12, 14, 15, and 17-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Snell in view of U.S. Patent Number 5,855,594 to Olive et al. Reconsideration is respectfully requested in light of the above claim amendments and the following remarks.

**REJECTION UNDER 35 U.S.C. §102**

Claims 1, 4-6, 7, 13, and 16 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,722,999 to Snell. Reconsideration is respectfully requested.

Claims 1 and 15 are directed to a system and corresponding method that performs automatic capture verification. The system of Claim 1 includes autocapture means that detects the presence or absence of captured cardiac events in response to applied pacing pulses. The system also includes control means that generates a visual representation of captured and non-captured events, where the visual representation is generated based on the detection of captured cardiac events and loss-of-capture events. Display means are provided to display the visual representation to a medical practitioner.

Thus, the claimed system is operative to detect captured cardiac events and loss-of-capture events during a capture verification test, and is further operative to generate visual representations that are based on those detections. As amended Claim 1 now recites, the control means is responsive to the determination of whether a pacing pulse achieved capture, or whether there was a loss of capture, and is operative to generate a corresponding visual representation based on that determination.

As an example of the visual representation, FIG. 3 depicts one embodiment where, for each pacing pulse delivered to the patient's heart, the word "CAPTURE" or "NO CAPTURE" is displayed with the ECG data, where "CAPTURE" signifies the determination by the system that the pacing pulse achieved capture, and "NO

PATENT

"CAPTURE" signifies the determination by the system that the pacing pulse failed to achieve capture. Thus, the visual representation claimed by Applicant is other than ECG data, and furthermore is based on a determination made by the system as to whether a pacing pulse captured the heart chamber or not.

In contrast, the Snell patent discloses a system that stores various historical medical data, including waveform data. Snell teaches that various tests may be performed, and that various data may be collected and recorded from those tests. One test that Snell discloses is a capture threshold test. The results of that test (the new threshold level) are merged into the historical patient data file. In addition, Snell discloses that markers may be used to annotate the waveform data.

The Snell system thus presents a medical practitioner with recorded waveform data, and the "results" from the capture threshold test. However, the waveform data is not a visual representation of captured and non-captured events that is based on a determination as to whether a pacing pulse achieved capture or not. Likewise, the "results" disclosed by Snell are not a visual representation based on a determination as to whether a pacing pulse achieved capture or not. Moreover, Snell does not teach or suggest using markers to label events as captured or loss-of-capture events.

It is well settled that in order for a reference to anticipate a claim, each and every element of the claim must be specifically disclosed by the reference. Here, such is clearly not the case. Snell does not disclose (or in any way suggest for that matter) a system that generates a visual representation of captured and non-captured events, where the visual representation is based on a determination as to whether pacing pulses captured the heart chamber or not. Therefore, it is respectfully submitted that the Snell patent does not anticipate any of Applicants' pending claims.

#### REJECTION UNDER 35 U.S.C. §103

Claims 2, 3, 8-12, 14, 15, and 17-22 were rejected under 35 U.S.C. §103(a) as being unpatentable over Snell in view of U.S. Patent Number 5,855,594 to Olive et al. Reconsideration is respectfully requested in light of the following remarks.

## PATENT

Pending Claims 15 and 22 are directed to a system and method that performs automatic capture verification. The system of Claim 15 includes autocapture means that performs automatic capture verification, and detection means that detects the presence or absence of captured cardiac events during the capture verification. The system also includes control means that identifies captured cardiac events and loss-of-capture events. The system further includes marking means for marking each captured event and loss of capture event with a predetermined visual representation.

Thus, the system of Claim 15 determines whether each pacing pulse captured the heart chamber and, based on that determination by the system, appropriate markers are displayed to the medical practitioner.

As set forth above, Snell in no way teaches or suggests a system that generates a visual representation to identify captured and loss-of-capture events, where the visual representation is based on a determination as to whether or not the pacing pulses captured the heart chamber. Snell simply discloses that a capture threshold test may be performed, and that the results of the test may be stored in a historical patient data file. However, those results are not a visual representation corresponding to a determination by the system of whether a pacing pulse was determined to have achieved capture or not.

Likewise, Olive et al. disclose a system that performs a capture threshold test. However, Olive et al. fail to teach or suggest providing visual representation that indicates whether the pacing pulse achieved capture or failed to achieve capture, where the visual representation is based on a determination by the system as to whether a pacing pulse achieved capture or not.

Neither Snell nor Olive et al., whether taken alone or in combination, teach or suggest a system that provides a visual representation of capture and loss of capture for each pacing pulse delivered during capture verification.

PATENT

**CONCLUSION**

In light of the above remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attachment is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE**".

Respectfully submitted,

8/13/02  
Date

Derrick Reed

Derrick Reed, Reg. No. 40,138  
Patent Attorney for Applicants

Pacesetter, Inc.  
15900 Valley View Court  
Sylmar, CA 91392-9221  
818/493-2200  
818/362-4795 (fax)

PATENT

VERSION WITH MARKINGS TO SHOW CHANGES MADEIn the Claims:

1. (Amended) A system for automating review of capture verification by a medical practitioner, the system being configured for use with an implantable stimulation device implanted in a patient and a programmer operated by the medical practitioner and configured to remotely communicate with the implantable stimulation device, the system comprising:

autocapture means for performing automatic capture verification through the implantable stimulation device to detect a presence of a captured cardiac event and an absence of a captured cardiac event when the captured cardiac event is expected;

control means, responsive to detection of presence and absence of captured cardiac events by the autocapture means, for generating a visual representation of the presence and absence of the captured cardiac event; and

display means for displaying the visual representation to the medical practitioner, to permit the medical practitioner to examine and analyze the performance of the automatic capture verification.

16. (Amended) A method for automating review of capture verification by a medical practitioner, the method being implemented in an implantable stimulation device implanted in a patient and a programmer operated by the medical practitioner and configured to remotely communicate with the implantable stimulation device, the method comprising [the steps of]:

performing an automatic capture verification through one of the implantable stimulation device or the programmer by adjusting the stimulation device's stimulation pulse energy and by detecting a presence and absence of [an] expected [captures] captured cardiac events;

PATENT

generating a visual representation of the automatic capture verification on an output device located in the programmer, the visual representation being [configured] based on detection of the presence and absence of captured cardiac events to identify a presence of the captured cardiac events when the captured cardiac event is detected, and to identify an absence of the expected captured cardiac event when the cardiac event is not detected.